Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA Directive 1100.18 Transmittal Sheet January 28, 2021

### REPORTING AND RESPONDING TO STATE LICENSING BOARDS

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive contains requirements for health care facilities' procedures regarding reporting and responding to State Licensing Boards (SLBs). **NOTE**: This directive does not apply to community providers performing care as part of a Community Care Network (CCN) or a Veterans Care Agreement. Community providers breaching the standard of care provided to veterans should be reported on the following SharePoint site managed by the VHA Office of Community Care:

https://vaww.cc.cdw.va.gov/sites/CC\_NetworkMgmt/NA/NM/Credentialing/\_layouts/15/start.aspx#/Lists/Field%20Request%20for%20Provider%20Hold

- **2. SUMMARY OF MAJOR CHANGES:** There are several technical changes in this document as it was originally a handbook converted into a directive. Additional significant changes include:
- a. Clarifies that reporting requirements include the reporting of all contract providers including those participating in Community Care agreements, which should be reported according to the guidance provide by the Office of Community Care.
- b. Removes reporting for statistical association and clarifies that reporting must be done when there is substantial evidence of substandard care performed by a licensed provider.
  - c. Adds requirements for completion of exit reviews including exit review template.
- d. Adds requirement for the Credentialing and Privileging Program Manager to be responsible for the SLB reporting process and oversight of timely completion of exit reviews;
- e. Adds requirement to include a comment on the appointment screen in the electronic credentialing file for licensed health care professionals who have left VA but whose exit review identified substandard care.
  - f. Removes requirement to send initial advisement notice to licensed provider.
  - g. Adds requirement to send the Evidence File with notice of intent to report letter.
- h. Removes requirement to send a second Notice of Intent to Report if the licensed health care professional does not respond within 7-business days, or if initial package is returned undeliverable.
- i. Clarifies that the provider has only 7-business days to respond from date of receipt of Notice of Intent to Report. The VA medical facility Director may grant a 7-business

day extension in extenuating circumstances. The Veterans Integrated Service Network (VISN) Director has authority to grant an additional 7-business days (maximum) in rare cases.

- j. Removes designation of sensitive versus non-sensitive cases.
- k. Removes requirement for review of cases by the Office of General Counsel (OGC).
- I. Clarifies review of a VISN assigned Privacy Officer to ensure compliance of documents of the Evidence File with the Privacy Act.
- m. Specifies that Privacy Officers have 7-business days to review a SLB file rather than 60-calendar days.
- n. Requires upload of documents into a SLB Reporting SharePoint site rather than routing on paper.
- o. Clarifies that the VA medical facility Director has ultimate authority in deciding whether to report a licensed provider and must document decision, which will be included in the Evidence File.
- 3. RELATED ISSUES: None
- **4. RESPONSIBLE OFFICE:** The Office of Quality & Patient Safety is responsible for the contents of this VHA directive. Questions may be addressed to the Office of Medical Staff Affairs at <a href="https://www.vhanton.org/v
- **5. RESCISSIONS:** VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards, dated December 22, 2005, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of January 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

# BY DIRECTION OF THE UNDER SECRETARY FOR HEALTH:

/s/ Gerard R. Cox, MD, MHA
Assistant Under Secretary for Health
Office of Quality & Patient Safety

**NOTE:** All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

**DISTRIBUTION:** Emailed to the VHA Publications Distribution List on February 2, 2021.

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#### REPORTING AND RESPONDING TO STATE LICENSING BOARDS

#### 1. PURPOSE

This VHA directive sets forth the policy and procedures to be carried out by the Veterans Health Administration (VHA) for: reporting licensed health care professionals to State Licensing Boards (SLBs) as a VHA initiative and responding to SLB in response to inquiries regarding current or separated VHA licensed health care professionals including VHA community providers. **AUTHORITY:** Title 38 United States Code (U.S.C.) §§ 7401 through 7405 and 7311 and Title 38 Code of Federal Regulations (C.F.R.) § 47.2.

**NOTE**: VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009, details the requirements for reporting to the NPDB.

#### 2. BACKGROUND

- a. VA has broad authority to report to SLBs those currently appointed or separated licensed health care professionals whose behavior or clinical practice substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients. This authority extends to full-time, part-time, intermittent, volunteer, or contract providers and is derived from 38 U.S.C. §§ 7401 through 7405. These statutes authorize the Under Secretary for Health, as head of VHA, to establish the terms and conditions of initial appointment and continued employment of VHA health care personnel.
- b. Pursuant to 38 U.S.C. § 7311 and 38 C.F.R. § 47.2, VA has established a comprehensive quality assurance program for reporting to an appropriate SLB any licensed health care professional who:
- (1) Was fired, resigned, or removed from a contract following the completion of a disciplinary action relating to such professional's clinical competence.
- (2) Resigned after having had such professional's clinical privileges restricted, reduced, or revoked.
- (3) Resigned after serious concerns about such professional's clinical competence had been raised, but not resolved.
- (4) Remain employed or appointed at a facility but has been identified as providing substandard care in one or more episodes of care to a patient(s).
- (5) Remain employed or appointed and provided substandard care in one or more episodes of care to a patient(s) but are undergoing the process of being removed from employment, appointment, and or contract.
- (6) Provided care to VA beneficiaries through community care contract or agreement and have been identified as providing substandard care to a VA

beneficiary via an arrangement between the community provider and the VA. **NOTE:** Community Care providers will be reported in accordance with guidance from the Office of Community Care.

- c. VA has a responsibility to protect the privacy rights of its current and former professionals in the reporting process. VA ensures such protection by conforming to the disclosure requirements of the Privacy Act, codified at 5 U.S.C. § 552a, when initiating disclosure or responding to inquiries from SLBs of information on current and former professionals. However, the guiding principle is making patient safety the paramount consideration.
- d. The rationale for reporting professionals under the continuing jurisdiction and supervisory control of VA for deficiencies which might impact on the safety of patients in a board's jurisdiction, is as follows:
- (1) Many licensed health care professionals who provide health care services to VA beneficiaries are not exclusively under the control of VA. These professionals may provide health care services to patients, other than VA beneficiaries, elsewhere under a board's jurisdiction. These professionals include part-time, intermittent, on-and off-station, full-time, and contract professionals who may be involved in health care activities outside their full-time VA employment.
- (2) VA must avoid even the appearance of sheltering or protecting its professionals from reasonable reporting standards which apply in the non-VA health care community.

#### 3. DEFINITIONS

- a. <u>Certification.</u> Certification is the documentation issued by a recognized health care organization or other established entity, such as a State attesting to minimum competence in a health care field.
- b. <u>Currently Employed Licensed Health Care Professional.</u> A currently employed licensed health care professional is any licensed health care professional who is on VA rolls for the provision of health care services, regardless of the status of the professional, such as full-time, part-time, contract service, fee basis, non-VA, or without compensation.
- c. <u>Generally accepted Standards of Clinical Practice.</u> Generally accepted standards of clinical practice mean reasonable competence in the clinical aspects of one's responsibilities, as well as the moral and ethical behavior necessary to carry out those responsibilities.
- d. <u>Licensed Health Care Professional.</u> A licensed health care professional (also referred to as "licensed health care provider" in this directive) is an individual appointed or utilized under Title 5 or Title 38 on a full-time, part-time, intermittent, off-station or on-station, fee-basis, non-VA; contract basis including contracts, or sharing agreement basis; either permanent or temporary, whether paid or without

compensation, who is licensed, certified or registered in a health care profession (such as but not limited to: a physician, dentist, podiatrist, optometrist, chiropractor, psychologist, nurse, expanded-function dental auxiliary, physical therapist, practical or vocational nurse, pharmacist, or social worker). As used in this Directive, the term licensed health care professional also refers to a licensed health care provider appointed to a position in an occupation where appointment in VA does not require licensure, but one is claimed, i.e., Physician Assistants As used in this Directive, it also refers to licensed individuals working outside their licensed occupation, such as a registered nurse appointed to a Title 5 position, in any organizational unit or section of VHA, including Network offices and Central Office, but only to the extent actions by such individuals relate to provision of direct clinical care. Community Care providers will be reported in accordance with guidance from the Office of Community Care.

- e. <u>Licensure.</u> Licensure is the official or legal permission to practice in an occupation, as evidenced by documentation issued by a State in the form of a license and/or registration.
- f. <u>Separated Licensed Health Care Professional.</u> A separated licensed health care professional is any licensed health care professional no longer on VA rolls and who left VA for any reason. This includes both voluntary and involuntary reasons, including disability retirement.
- g. <u>Substantial Evidence.</u> Substantial evidence is the degree of relevant evidence that permits a reasonable person might accept as adequate to support a conclusion, even if it is possible to draw contrary conclusions from the evidence, for believing that the professional so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients or the community. Substantial evidence of wrongdoing is more than mere suspicion, or uncorroborated hearsay or rumor.

**NOTE:** For SLB reporting purposes, this definition focuses more on the quality and credibility of the evidence than the quantity of the evidence.

h. 38 U.S.C. § 5705 – Confidentiality of Medical Quality-Assurance Records. Records and documents created by the Department as part of a medical quality-assurance program for the purpose of improving the quality of medical care or improving the utilization of health-care resources in the agency and designated as 38 U.S.C. § 5705 protected. Documents under this protection may not be utilized as evidence for reporting to a state licensing board. Episodes of care identified through a protected process must be "rediscovered" through a non-protected management review process.

#### 4. POLICY

It is VHA policy to report to SLBs regarding current or separated VHA licensed health care professionals including VHA community providers when substantial

evidence supports a reasonable conclusion that the professional's clinical practice during VA employment so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients or the community. t is also VHA policy to cooperate with SLBs when they submit an inquiry, compliant with the Privacy Act, regarding current or separated VHA licensed health care professionals including VHA community providers.

#### **5. RESPONSIBILITIES**

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this Directive.
- b. <u>Assistant Under Secretary for Health for Quality & Patient Safety</u>. The Assistant Under Secretary for Health for Quality & Patient Safety is responsible for supporting the Medical Staff Affairs Director with implementation and oversight of this directive.
- c. <u>Assistant Under Secretary for Operations</u>. The Assistant Under Secretary for Health for Operations is responsible for:
- (1) Communicating the contents of this directive to each Veterans Integrated Services Network (VISN).
- (2) Providing assistance to VISN Directors to resolve implementation and compliance challenges.
- (3) Providing oversight of VISNs to assure compliance with this directive and its effectiveness.
- c. <u>Medical Staff Affairs Director</u>. The Medical Staff Affairs Director is responsible for serving as the VHA subject matter expert for reporting and responding to SLBs.
- d. <u>Veterans Integrated Service Network Director</u>. The VISN Director is responsible for:
- (1) Ensuring VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.
- (2) Assigning a Privacy Officer within the VISN who will be responsible for reviewing SLB reporting files in accordance with this Directive to ensure compliance with the Privacy Act.
- e. <u>VA Medical Facility Director</u>. The VA medical facility Director has the ultimate decision authority of whether the clinical care provided to a VA beneficiary so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients or community, such that reporting to an SLB is warranted. The VA medical facility Director is responsible for:

- (1) Ensuring that no settlement agreement offered to an employed or separated licensed health care professional prohibits VA from reporting the professional to their respective SLBs, where reporting would otherwise be warranted. (See paragraph 7.)
- (2) Ensuring Provider Exit Review forms are completed on all licensed health care professionals, including volunteers and contractors, who leave their positions at the facility for any reason within 7-business days of departure. **NOTE:** Exit review forms do not need to be completed on residents or trainees, unless they were credentialed and privileged to practice independently such as a Chief Resident or Resident who was privileged to independently work in an Emergency Room.
- (3) Ensuring Provider Exit Review forms are maintained at the facility and that a copy of the completed form is scanned into the provider's electronic credentialing file (on the Provider Profile screen of the electronic credentialing file) prior to the file being deactivated.
- (4) Ensuring the SLB reporting process is initiated within 7-business days of awareness that a licensed health care professional has potentially failed to meet generally acceptable standards of care beginning with the initial review stage to establish whether there is substantial evidence of the failure to meet standard of care.
- (5) Prompt completion of the reporting process as outlined in this Directive once substantial evidence is established supporting a reasonable conclusion that a licensed health care provider significantly failed to meet generally accepted standards of clinical practice.
- (6) Identification of appropriate reviewers and support to complete review process. To ensure objectivity, consideration of obtaining expert reviewers outside of the facility through the VISN or VACO program specialty areas should be made.
- (7) Documenting their decision and reason for not reporting on the Decision Memorandum for VA medical facility Director (Appendix F).
- f. <u>VA Medical Facility Credentialing and Privileging Manager</u>. The VA Medical Facility Credentialing and Privileging Manager is responsible for reporting licensed providers to respective state licensing boards in accordance with this directive. Responsibilities include but are not limited to:
- (1) Establishing system to obtain Exit Review Forms upon departure of licensed providers within 7 business days of departure.
- (2) Scanning Exit Review Forms into the licensed provider's electronic credentialing file in VetPro on the Personal Profile screen upon receipt prior to inactivating the file.
- (3) Initiating SLB reporting process within 7-business days of signature of the supervisor on the of an Exit Review Form which indicates that licensed provider

failed to meet the standard of care.

- (4) Initiating SLB reporting within 7-business days of the Executive Committee of the Medical Staff recommending to the VA medical facility Director that a privileging action be taken on a privileged licensed independent practitioner.
- (5) Developing and maintaining SLB reporting files which contain all evidence and forms outlined within this Directive.
- (6) Maintaining a file of Exit Review Forms in which provider specific forms may be retrieved for review or auditing purposes.
- (7) Entering State Licensing Board reporting information into the NPDB/SLB Tracker.
- g. <u>VHA Employees.</u> VHA employees have the responsibility to expeditiously bring concerns of substandard care or clinical performance of a VHA licensed health care provider to their supervisor and/or medical center leadership. VHA Employees do not have authority to independently report current or former VHA licensed health care providers to the SLB based upon knowledge they have obtained as a result of their VHA related duties. The concerns must be thoroughly evaluated and information only released to the SLB after review and decision of the VA medical facility Director and in compliance with the Privacy Act and this directive.

#### 6. VA-INITIATED REPORTING OF HEALTH CARE PROFESSIONALS TO AN SLB

- a. VA medical facilities must report on their own initiative, after determining, through the process defined in this directive, that the appropriate Privacy Act requirements have been met, each licensed health care professional whose behavior or clinical practice so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients. The report must be submitted to each SLB where the professional holds a license as well as to the respective SLB in the state in which the professional is practicing, if not licensed in that state.
- b. The following is a non-exhaustive list of actions which provide a reasonable basis for concern for the safety of patients and, as such, should be reported:
- (1) Significant deficiencies in clinical practice are not limited to: lack of diagnostic or treatment ability; multiple errors in transcribing, administering, or documenting medications; inability to perform clinical procedures considered basic to the performance of one's occupation; or performing procedures not included in one's clinical privileges in other than emergency situations.
  - (2) Patient neglect or abandonment.
- (3) Mental health impairment sufficient to cause the licensed health care professional to make errors in judgment affecting patient safety, behave inappropriately in the patient care environment, or provide unsafe patient care.

- (4) Physical health impairment sufficient to cause the licensed health care professional to provide unsafe patient care.
- (5) Substance abuse which affects the individual's ability to perform appropriately as a health care provider or in the patient care environment. Note: Drug tests on employees performed by a VHA facility lab are not disclosable to State Licensing Boards as they are part of both the Employee Medical Record and the Privacy Act system of records "Patient Medical Records-VA", 24VA10P2 and are subject to 38 U.S.C. § 7332 unless written authorization to disclose is obtained by the provider.
  - (6) Falsification of credentials.
  - (7) Falsification of medical records or prescriptions.
  - (8) Theft of drugs.
  - (9) Inappropriate dispensing of drugs.
- (10) Unethical behavior or moral turpitude, such as sexual misconduct toward any patient involved in VA medical care.
- (11) Patient abuse, including but not limited to mental, physical, sexual, and verbal abuse, including:
- (a) Any action or behavior that conflicts with a patient's rights identified in statute, regulation, or VA/VHA policy.
  - (b) Intentional omission of care.
  - (c) Willful violations of a patient's privacy; or
  - (d) Willful physical injury, intimidation, harassment or ridicule of a patient.
- (12) Falsification of research findings, regardless of where the research was carried out or the funding source, as long as the research involved some aspect of VA operations.
- c. When a decision is reached to initiate SLB reporting regarding a currently employed licensed health care professional, a decision may also be made to initiate appropriate disciplinary or other Human Resources proceedings or to place the professional in a non-clinical environment.
- d. In accordance with VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, a copy of the NPDB report must be submitted to the licensed health care provider's respective SLB(s). This process is only providing a copy of the NPDB report which has limited information and does not meet the requirements of this directive. **NOTE:** Reporting under the requirements of one VHA policy does not relieve the VA medical facility from meeting its obligation under any other VHA policy, e.g.,

requirements to report to an SLB in accordance with VHA Handbook 1100.17 National practitioner Data Bank (NPDB) Reports. Reporting of substandard care may occur before a tort claim is settled or the case is reviewed by the Office of Medical Legal Affairs (OMLA) if there is substantial evidence available. If OMLA has indicated that a licensed health care professional should be reported to a SLB(s), full SLB reporting should also occur in accordance with this Directive. In rare instances OMLA may identify substandard care but based upon evidence, the VA medical facility Director decides not to report the provider to the SLB. The VA medical facility Director must document their decision and reason for not reporting on the Decision Memorandum for VA medical facility Director (Appendix F).

- e. A VA-initiated report to a SLB is only notice to the SLB that there is a question of a professional's clinical practice or behavior. Accordingly, the report is not a VA action against a professional's license, and VA has no authority to require a SLB to take any action against a reported professional's license. The SLB may or may not, according to its standards, follow up and obtain relevant portions of the VA SLB Reporting File or undertake formal proceedings against the license of the professional, and all such proceedings, including the professional's right to a hearing, are governed by the SLB's policies and procedures.
- f. SLB reporting must be initiated as soon as there is substantial evidence of the provider significantly failing to meet the generally accepted standards of clinical practice to raise reasonable concern for the safety of patients. SLB reporting must not wait until a personnel action has been completed or until a related hearing process has concluded such as a Disciplinary Appeals Board (DAB) or Summary Review Board. The SLB reporting process should occur concurrently to personnel actions or privileging actions, often using a significant amount of the same evidence. SLB reporting must be initiated within 7-business days of the Executive Committee of the Medical Staff (ECMS) proposing a privileging action that is based upon evidence of substandard care to the VA medical facility Director. The report to the SLB is not the proposed privileging action in and of itself, rather the evidence of substandard care that was utilized by the ECMS to base their recommendation.
- g. Charges and evidence used to report a licensed professional to a SLB must have a nexus to substandard care provided during their duties as a VHA licensed health care provider or community care provider paid by VA to treat VA beneficiaries. Straight conduct issues such as insubordination, tardiness, failure to follow instruction, etc. to which there is no nexus to patient care or outcome are not reportable to SLBs and are managed through Human Resource (HR) disciplinary action processes as applicable.

# 7. ENTERING AGREEMENTS THAT WOULD PROHIBIT OR RESTRICT DISCLOSURE

VA medical facility Directors, other medical facility employees, or any individual purportedly acting on behalf of VA are prohibited from entering into any express or implied agreement that would prohibit or interfere with the reporting of a licensed health care professional to an SLB, or that would destroy or remove any information

needed in the review process, in return for the licensed health care professional's agreement to a personnel action, such as resignation, retirement, or reassignment. Any such purported agreement is not binding upon VA and may form the basis for administrative and disciplinary action against any VA employee who participated in the inclusion of such prohibited settlement term or provision or approved the settlement agreement including aforementioned prohibited settlement term or provision.

#### 8. THE SLB REPORTING STAGES; CREATING AND FILING RELATED RECORDS

- a. The SLB Reporting Program involves five stages:
- (1) Initial Review Stage:
- (2) Comprehensive Review Stage;
- (3) Decision Stage;
- (4) Privacy Officer Review Stage; and
- (5) The Reporting Stage.

**NOTE:** These five stages should be completed in less than 100-calendar days. An overview of the tasks, records are to be created, and procedures are provided in Appendix A with suggested timeframes. Instructions for compiling and organizing the SLB reporting file are contained in Appendix B.

b. The records created or compiled in connection with this reporting, including Provider Exit Review forms and documents from any stage of reporting, are to be filed and retrieved by the name of the licensed health care professional and are to be maintained in Privacy Act System of Records 77VA10A4, Health Care Provider Credentialing and Privileging Records – VA, regardless of whether the professional has an electronic credentialing file within the VA. Specifically, the file must be maintained on site for 3 years after VA employment ends or 3 years after reporting, and then must be retired to the VA Records Center and Vault to be maintained for 30 years before destruction.

#### 9. THE INITIAL REVIEW STAGE

- a. Licensed Health Care Professionals Who Has Left the VA medical facility: Exit Reviews:
- (1) The VA medical facility Director must ensure that within 7-business days of the date a licensed health care professional leaves their facility (e.g., termination, resignation, disability retirement, end of contract, or transfer) an Exit Review is conducted by the individual's first- or second-line supervisor. This review must be conducted to confirm that the licensed provider's clinical practice met the standard of care during the provider's professional relationship with the facility. If the supervisor

indicates, based upon documented substantial evidence, that the licensed health care professional failed to meet the generally acceptable standards of care, the process for preparing a report to the appropriate SLB must be initiated within 7-business days of the date of the signature of the supervisor. The document must be circulated for signatures of higher-level review officials within those five days. Signatures may be electronic. The exit review must be documented on the on the template in Appendix J of this directive.

- (2) The Credentialing and Privileging Program Manager must collect all Exit Reviews and initiate SLB reporting on any licensed health care professional who has been noted as failing to meet the generally accepted standard of care. This individual should work closely with both HR and the Contracting Officer's Technical Representative(s) for clinical contracts and must be provided a list of licensed health care professionals who are separating from the facility. This list should identify the final date of employment with the facility (e.g., losses from resignation, terminations, transfers, or termination of clinical contract) on at least a monthly basis. A Provider Exit Review form must be obtained within 7-business days of the final date of employment for each of the listed individuals.
- (3) Provider Exit Review forms must be maintained in a secured location that is accessible only to those with a need to know. The forms can be maintained through electronically, such as in a restricted SharePoint site and remain retrievable at the facility for 3 years after departure of the licensed provider.
- (4) If there is substantial evidence of substandard care for the respective provider (who has left the facility), the following comment must be entered into the comments section of the Appointment screen in the provider's electronic credentialing file: "An exit review was conducted on this provider and there was substantial evidence of substandard care performed while at this VA medical facility. The SLB reporting process, beginning with a comprehensive review, was initiated." The Credentialing and Privileging Program Manager is to ensure this comment is entered into the provider's electronic credentialing file. This will serve as an alert to facilities where the provider may apply in the future.
- b. Licensed Health Care Professional Currently Appointed at a VA Medical Facility (including volunteers, staff, and contractors).
- (1) The first- or second-line supervisor must initiate the SLB reporting process within 5-business days of obtaining objective evidence that the licensed health care professional failed to meet the generally acceptable standards of care. The supervisor must immediately make a recommendation to their respective quadrad member (e.g., chief of staff, associate director, associate director for patient care services) if the licensed health care provider should be removed from patient care based upon the evidence at hand. For privileged providers, a summary suspension of one or more privileges should be initiated if appropriate based upon the circumstances. For non-privileged providers, administrative reassignment through Human Resources should be initiated if appropriate based upon the circumstances.

(2) The Credentialing and Privileging Program Manager must be notified by the supervisor in no more than 7-business days of identification of substandard care so that the SLB reporting process can be immediately initiated.

### 10. THE COMPREHENSIVE REVIEW STAGE

a. Failure to Meet Accepted Standards. When the initial review suggests that there may be substantial evidence that the licensed health care professional so failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients, the VA medical facility Director, or head of the VA medical facility's appropriate organizational component, is responsible for ensuring that a comprehensive review has been initiated within 7-business days to determine whether there is, in fact, substantial evidence that the licensed health care provider has failed to meet generally accepted standards of clinical practice. This review involves the preparation of an SLB Reporting File. The objective of the comprehensive review is to present a balanced and complete picture in the file of the circumstances which formed the basis for the concern.

### b. **Evidence.**

- (1) The individual who is preparing the file must collaborate with the specialists involved in the comprehensive review to identify in the review any significant conflicting evidence, make reasonable effort to determine which side of the conflicting evidence has stronger supporting evidence, and set out in the review, the rationale for believing one position over another.
- (a) The comprehensive review may or may not conclude that there is substantial evidence that there was substandard care; and/or
- (b) That some or all of the substandard care creates a reasonable concern for the safety of patients regarding each concern.
- (2) Prior to sending the Notice of Intent to Report (see subparagraph (d) below), evidence gathered must provide substantial evidence to support each allegation listed in the letter. Evidence gathered but determined not to be substantial evidence that would support an allegation in the Notice of Intent to Report is to be removed from the Evidence File but preserved and marked "Review Material Not Substantial Evidence" and maintained as marked in System of Records 77VA10A4, Health Care Provider Credentialing and Privileging Records VA, under the professional's name.
- c. <u>Evidence File.</u> The SLB Evidence File consists of three parts: the Evidence File, Notice of Intent to Report, and the Response and Rebuttal Resolution Memorandum. The Evidence File must be prepared as required by this Directive. All parts of the file must be compiled and organized in accordance with the instructions in Appendix B and redacted in accordance with paragraph 10(e).

#### d. Notice of Intent to Report.

- (1) When the Evidence File indicates that there is substantial evidence that the reporting standard has been met, a Notice of Intent to Report and evidence supporting each allegation outlined in the Notice of Intent to Report must be provided by the reviewer to the licensed health care professional. A notice assists in satisfying information law requirements that reasonable efforts be made to ensure that the Evidence File information is accurate, relevant, and complete. Each licensed health care professional being considered for reporting to an SLB must be provided a notice or at least a reasonable attempt to provide a notice is to be made. The notice must list each allegation and must describe the facts giving rise to each allegation. The description must be sufficiently clear and precise so that the professional can understand exactly what circumstances are giving rise to each allegation and what was the exact wrongdoing. An allegation not contained in the notice may not be disclosed to an SLB. Accordingly, it is important to have completed a thorough review prior to sending this Notice of Intent to Report. If additional evidence is discovered, a new Notice of Intent to Report with the additional charges must be sent to the provider. Accordingly, the Index of Charges from the Evidence File must be copied verbatim into the Notice of Intent to Report, except for tab page references and patient identifiers, which must not be included. In order to meet information law requirements, the content of the Notice of Intent to Report must conform to the sample Notice of Intent to Report letter contained in Appendix D. If there are questions related to redactions that should be made to the evidence prior to the notice being sent to the licensed health care professional, the local Privacy Officer or supporting Chief Counsel in the District should be consulted.
- (2) The Notice of Intent to Report requirement is satisfied by mailing the notice to the licensed health care professional by Certified Mail, Return Receipt Requested. Proof of notice, such as a signed Certified Mail Return Receipt or an affidavit of personal delivery when handed directly to the provider, must be added to the SLB Reporting File in the location indicated in Appendix B. If the licensed health care provider cannot be reached, the Notice package should be mailed to his/her last known address. The licensed health care provider will be given 7-business days to respond from the date of receipt. In extenuating and rare circumstances, the VA medical facility Director may grant an extension, not to exceed 7-business days. If the package is returned undeliverable or a response or rebuttal from the licensed health care provider is not received within the time allowed for response, the process of reporting to the SLB(s) must proceed to the Decision Stage discussed in section 12, The Privacy Review Stage, below.
- e. **Redactions**. The following must be redacted at the VA medical facility level in the Evidence File that is sent to the licensed health care professional and SLB:
- (1) Patient Identifiers should be excluded from the reporting file. Personal identifiers including any information that makes the information linkable to an individual should be removed prior to inclusion in the reporting file. General identifiers can be used in the file and the VA medical facility must have a crosswalk so that they can easily identify the referenced patients. If the provider requests the specific patient identifier in order to perform a more extensive review, the VA

medical facility will provide the information within 7-business days so that the licensed health care provider has opportunity to review and respond.

- (2) Personal information of the subject or other licensed health care providers that are not pertinent to the episode of care related to the allegation should be redacted or removed prior to submission to the licensed health care provider or the SLB.
- (3) Personal identifiers of staff other than the subject that are not pertinent to the episode of care related to the allegation should be redacted or removed prior to submission to the licensed health care provider or the SLB.
- (4) Medical information pertaining to the licensed health care provider being reported should be redacted or removed prior to submission to the licensed health care provider or the SLB.
- (5) The VA medical facility level Privacy Officer may be consulted on the redaction process and if there are questions related to compliance with the Privacy Act. The VISN Privacy Officer will have responsibility for the final review to ensure compliance with the Privacy Act in the final Privacy Review Stage of the reporting process prior to sending the evidence file to the SLB. The review by the VISN Privacy Officer must be completed within 7-business days and returned to the VA medical facility.
- f. Response of the Professional and Rebuttal Resolution Memorandum. Whenever a licensed health care professional contests any of the allegations in the Notice of Intent to Report, the reviewer responsible for the reporting process must consult with the provider's current or former supervisor, or other provider of the same profession with same skills and privileges for consideration of each contested allegation, and must address each in a Rebuttal Resolution Memorandum similar in format to the sample in Appendix E. The reviewer must consider the evidence on both sides of a contested point and make a recommendation to the VA medical facility Director on which to believe. Making this recommendation may involve obtaining additional evidence. The reviewer must explain how the conflict was resolved. The resolution might involve the credibility of one person over another; where that is the case, a short explanation must be entered in the Memorandum. The licensed health care professional's response may demonstrate that a particular allegation is unfounded; in that case, the allegation and the supporting evidence must be deleted wherever it appears in the SLB Reporting File before the File is forwarded for concurrence. Such evidence must be preserved and marked "Notice to Report – Not Substantial Evidence" and maintained as marked in 77VA10A4 under the licensed health care professional's name. The Response and Rebuttal Resolution Memorandum material must be added to the SLB Reporting File at the point indicated in the guidelines in Appendix C. If a licensed health care provider does not submit a rebuttal within the required timeframe, a page should be entered into the evidence file noting the date the Notice of Intent to Report was sent, the method of which it was sent, and that there was no response from the provider by

the established timeframe. The SLB reporting process is to continue if the deadline for the licensed health care provider to respond has passed and no response was received.

**NOTE:** For additional guidance see the discussion of Resolution of Conflict in the Unit of Evidence in Appendix B.: It is the intent of this policy to make determinations based on all information reasonably and timely available. However, strict adherence to time limits must not be utilized to defeat this process. It is expected that VA would consider a late reply to a Notice of Intent to Report letter; similarly, late action by VA would not be a bar to further processing or to reporting.

#### 11. THE DECISION STAGE

- a. Upon completion of the Comprehensive Review Stage, the VA medical facility Director must decide whether to report the licensed health care professional to the SLB. The entire SLB Reporting File, including the Evidence File, Notice of Intent to Report File, and Response and Rebuttal Resolution Memorandum materials, must be considered in determining whether there is substantial evidence that, as to each allegation in question, the professional so substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients. The determination will be made within 7-business days after the Comprehensive Review Stage has been completed. The VA medical facility Director is the final authority who determines whether a licensed health care provider will be reported to the SLB(s).
- b. There is no minimum or maximum number of permitted allegations. Three or four allegations taken together may result in a sufficient basis to warrant reporting even though none of them individually would do so. On occasion, during the Comprehensive Review process, some or even all of the allegations may be dropped. Where some but not all of the allegations are dropped, the remaining allegations may or may not be sufficient to warrant reporting. One allegation of a serious nature may be sufficient to warrant reporting.
- c. The VA medical facility Director may wish to consult with and consider recommendations from appropriate clinical service chiefs as to whether the reporting standard has been met for each of the allegations.
- d. The VA medical facility Director must add a Decision Memorandum to the file following the format in Appendix F. The Decision Memorandum must contain the following information:
- (1) A statement that the VA medical facility Director has made a decision based upon consideration of the entire SLB Reporting File to report a licensed health care professional, providing the name and professional title of the individual and the SLB to whom the report is to be made;
- (2) Intended Reporting Statement. In accordance with Congressional intent to maintain appropriate confidentiality for the professional, the intended reporting

statement is to be limited to a generic description of the clinical shortcomings involved, such as, "Dr. Fictitious W. Jones so failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients when Dr. Jones repeatedly erred in the selection of appropriate medications."

#### 12. THE PRIVACY REVIEW STAGE

Within 7-business days of deciding to make a report to an SLB, the VA medical facility Director must send a complete Evidence File, with redactions made as necessary and tabbed as outlined in Appendix B to their VISN Director for assignment to the VISN Privacy Officer to review SLB Reporting Files. The VISN Director must ensure the assigned VISN Privacy Officer receives the file within 3-business days of receipt. The file must be reviewed by the assigned VISN Privacy Officer within 7-business days of receipt following the guidance outlined in Appendix C. The file is to be returned to the respective VA medical facility Director with a completed File Review Memorandum as outlined in Appendix G. If there is a concern of conflict of interest, objectivity, or timeliness the VISN Director may seek assistance from another VISN Director and their respective Privacy Officer. Timeframes still apply in these circumstances.

**NOTE**: A full unredacted copy of the Evidence File must be maintained at the VA medical facility in accordance with this directive.

#### 13. THE REPORTING STAGE

After the SLB Evidence File has been reviewed by the VISN-assigned Privacy Officer and required changes are made, the VA medical facility Director must send a reporting letter (see sample in Appendix H) to the relevant SLB within 7-business days of receipt from the Privacy Officer who reviewed the Evidence File. The letter must include the medical title of the professional, a generic description of the allegations being reported, and what the SLB must do to obtain detailed information on the matter. A copy of the letter submitted to the SLB must be uploaded into the SLB Reporting SharePoint site concurrently with the mailing of the letter to the SLB. Any letter from the SLB requesting follow-up information received by the VA medical facility should be forwarded to the VA medical facility Privacy Officer for review to confirm requirements of the Privacy Act have been met. The final redacted Evidence File can then be sent to the SLB.

#### 14. RESPONDING TO INQUIRIES FROM SLB

#### a. General

(1) It is VHA policy to cooperate whenever possible with an inquiry by an SLB. Accordingly, consistent with the procedures set out in this directive and in accordance with the Privacy Act, HIPAA Privacy Rule, 38 U.S.C. §§ 5701 and 7332, VA medical facilities must provide reasonably complete, accurate, timely, and relevant information to an SLB in response to inquiries related to the evidence submitted to the SLB in accordance with this Directive. For example, if a VA medical facility Director concludes,

following a Comprehensive Review conducted in accordance with this directive, that the reporting standard has not been met and the VA inquiry is properly terminated, VA will ordinarily cooperate with a subsequent inquiry initiated by an SLB, including making relevant portions its SLB Reporting File available pursuant to a Privacy Act request under 5 U.S.C § 552a(b)(7) and the health care operations and health oversight provisions of the HIPAA Privacy Rule (45 CFR 164.506(c) and164.512(d)), rather than to raise a Constitutional Federal Supremacy objection. The SLB is to be notified in writing that the VA medical facility Director did not deem the licensed health care professional reportable based upon extensive review of the evidence. Charges and evidence are not to be provided to the SLB that has not been first reviewed through the process outlined in this directive including the opportunity for the licensed health care professional to review and submit a written rebuttal. Information provided must be compliant with the Privacy Act and be reviewed by the VISN Privacy Officer to ensure compliance.

- (2) Because of the Privacy Act and HIPAA Privacy Rule, a standing request for information, such as a request for information to be provided each time there is a clinical practice concern, cannot be honored. The SLB must request specific information on a licensed health care professional by a signed consent or Privacy Act law enforcement investigation letter that satisfies the requirements outlined in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, similar to the sample Letter of Inquiry from SLB found in Appendix I. If the specific information on a licensed health care professional includes any health information of a patient, authority for providing such information under the HIPAA Privacy Rule must be present. Reporting of information to the SLB and providing upon request additional information in regards to the case is authorized under the HIPAA Privacy Rule as a health care operations and health oversight activity (45 C.F.R. §§ 164.506(c) and 164.512(d)).
- (3) Occasionally the Freedom of Information Act (FOIA) is cited by SLBs as authority to request information on professionals. Generally, FOIA does not permit disclosure about specific professionals or the related patient information. SLBs need to be advised to request the information with a signed consent from the individual in question, court order or with a Privacy Act, 5 U.S.C. § 552a(b)(7), Law Enforcement Investigation Letter as outlined in subparagraph 15c. However, a letter from a SLB that references FOIA but meets all of the requirements of a Privacy Act, 5 U.S.C. § 552a(b)(7) request should still be processed under the Privacy Act and not denied under FOIA.

### b. Signed Consent.

- (1) A signed consent from the subject licensed health care professional is sufficient to allow disclosure of information covered by the Privacy Act about either a currently employed or separated licensed health care professional, in response to a request from an SLB accompanied by the consent.
- (2) When relying on the signed consent for disclosure authority, the consent must have been signed within the 6 months prior to the date of the disclosure. The signed

consent must state the individual or organization to whom the information may be released and the type of information that may be released. It is suggested that all release of information be handled with the advice and consent of the local Privacy Officer. Clarification may be sought from the District Counsel by the Privacy Officer in questionable cases, such as when VA receives a signed consent that specifies that VA may release any information "other than information that is derogatory," or, when the consent does not specify the type of information that VA may release.

**NOTE:** The signed consent of the professional does not provide disclosure authority to release any patient information in the SLB Reporting File. It only provides disclosure authority to release personal information of the professional.

- c. Privacy Act 5 U.S.C. § 552a(b)(7), Law Enforcement Investigation Letter. Generally, information compiled to meet the requirements of this directive will be released if an SLB's request for that information meets the requirements of the Privacy Act, 5 U.S.C. § 552a(b)(7), following essentially the format of the sample Privacy Act section 552a(b)(7), Law Enforcement Investigation Letter, in Appendix I. The request must:
  - (1) Be in writing on the SLB's letterhead stationery.
- (2) Cite the State law giving the SLB authority to take action against professionals who hold such a license, certification, or registration.
- (3) Identify the individual by name or title about whom information is sought, the records desired, and the law enforcement activity for which the information is sought.

**NOTE:** This would usually indicate protection of the health of the State's citizens.

- (4) Be signed by the head of the SLB or a person who has been designated to act for the head of the SLB. If a designee is to sign the request letter, to be effective:
- (a) The designee must be an official of sufficient rank to ensure that the request for records has been the subject of a high-level evaluation of the need for the information, even considering the privacy interests of the professional involved. Such an official would be at least at the supervisory level.

**NOTE:** Generally, a request signed by a line investigator is insufficient.

- (b) The designation from the head of the SLB to the designee must accompany the request and must state that the designee is authorized to make a request under the section Privacy Act, 5 U.S.C. § 552a(b)(7).
- (c) Such a letter needs to be substantially similar to the sample Privacy Act, 5 U.S.C. § 552a(b)(7) letter contained in Appendix I. A copy of this sample law enforcement request letter needs to be provided to the SLB to assist them in complying with this disclosure requirement.

- (d) If there is any doubt, the VA medical facility Director, needs to consult with the local Privacy Officer, and as needed, District Counsel, to ensure that the SLB's law enforcement request complies with the Privacy Act requirements.
- d. <u>Subpoena.</u> Occasionally, a SLB requests information pertaining to a professional by administrative or state court subpoena. The SLB needs to be advised that disclosure can be made with a signed consent, court order, or by a Privacy Act, 5 U.S.C. § 552a(b)(7) law enforcement investigation letter (see Appendix I). Questions concerning subpoena requests need to be referred to District Counsel.

# 15. INTERIM RESPONSE TO A SLB INQUIRY WHEN VA IS CONSIDERING REPORTING ON ITS OWN INITIATIVE

When a request for information concerning a licensed health care professional is received from an SLB while a VA medical facility is considering reporting the individual, the facility needs to respond to the initial inquiry by stating that the SLB 's request is considered a serious matter; that a VA inquiry into this matter has been initiated; and that the request is being processed. The facility needs to expeditiously follow the five stages of procedures set forth regarding VA-initiated reporting (see Appendix A). The VA medical facility will not provide information to the SLB concerning the individual until after all procedures required for VA reporting have been met.

#### 16. TRAINING

- a. There are no required trainings associated with this directive.
- b. There are no recommended trainings associated with this directive.

#### 17. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule (RCS) 10-1. Any questions regarding any aspect of records management should be directed to the VA medical facility Records Manager or Records Liaison. See also VHA Directive 6300, Records Management, or subsequent policy issue.

#### 18. REFERENCES

- a. 5.U.S.C. § 552a
- b. 5 U.S.C. §§ 7361, 7362
- c. 38 U.S.C. § 501
- d. 38 U.S.C. §§ 5701, 5705

- e. 38 U.S.C. §§ 7311, 7332, 7401 7405
- f. 42 U.S.C. § 290dd
- g. 38 C.F.R. § 1.461
- h. 38 C.F.R. § 17.501
- i. 38 C.F.R. § 47.2
- j. 45 C.F.R. §§ 160, 164.501, 164.506 and 164.512
- k. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.
- I. VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009.

#### APPENDIX A

# OVERVIEW OF THE FIVE STAGE STATE LICENSING BOARD REPORTING PROCESS

For an overview of the five stage state licensing board reporting process map, please visit the following Web site:

https://vaww.qps.med.va.gov/divisions/qm/msa/AdverseActions/aaLanding.aspx.

NOTE: This is an internal VA Web site that is not available to the public.

#### **APPENDIX B**

# INSTRUCTIONS FOR COMPILING, ORGANIZING AND PREPARING THE STATE LICENSING BOARD REPORTING FILE AND DECISION MEMORANDUM: GUIDANCE FOR PRIVACY OFFICERS ON REPORTING FILE REVIEW

#### 1. BACKGROUND

- a. To ensure that its health care professionals meet generally accepted professional standards for patient care, the Department of Veterans Affairs (VA) notifies State Licensing Boards (SLB), charged with licensing health care professionals, when a professional's behavior or clinical practice so substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients (see Sections. 1-5).
- b. A facility reports a professional to the appropriate SLBs by submitting a Reporting File, which contains an Evidence File of documentation supporting the charges of substandard care. Records that may appear in an Evidence File include: patient medical records, including prescription and administration control records; documents of administrative boards of investigation; police reports; signed statements and reports of contact from the professional, staff, or patients; facility policies and procedures that identify the standards or requirements breached; and relevant health information specific to the licensed health care professional (see App. B, subpar. 1d).

#### 2. DISCLOSURE AUTHORITY

- a. The Privacy Act permits VHA to release to an SLB the Evidence File concerning a health care professional pursuant to the professional's prior written consent or a qualifying request from the SLB (see 5 U.S.C. 552a(b)(7) the Privacy Act)). The routine use in the "Patient Medical Records VA" system of records (24VA10P2) regarding disclosures to SLBs does not provide authority for the disclosure of the Evidence File. Under the routine use, VA may alert a SLB of incidents suggesting substandard care, without naming the licensed health care professional, and indicate that the Evidence File may be provided pursuant to a qualifying law enforcement request. The release of any more information, including the Evidence File, must be authorized by either a written consent of the professional or a law enforcement request that qualifies under section (b)(7) of the Privacy Act. **NOTE:** For a sample letter that meets the requirements for a proper law enforcement request, see Appendix I.
- b. To the extent that the Evidence File contains individually-identifiable health information, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorizes VHA to disclose such materials in conducting its health care operations. The definition of health care operations includes: the review of the competence or qualifications of a health care professional, as well as accreditation, certification, licensing, and credentialing activities. Accordingly, VHA may provide the SLB with an Evidence File that contains individually-identifiable health information to conduct its health care operations (see 45 C.F.R. §§ 164.501 and 164.506(c)(1)) and in compliance with section 3a. of this Appendix.

### 3. Categories of Records and Information

- a. Individual Identifiers. Information that identifies individual patients, including names, addresses, and social security numbers, must be redacted from all documents. Names of VA employees may generally remain in the Evidence File, although their home addresses, telephone numbers, and Social Security Numbers must be redacted. To assist the reviewer where more than one patient is involved, individual identifiers may be replaced anonymous patient identifiers, such as Patient W (see VHA Directive 1100.18, App. B, par. 2b(1)).
- b. Title 38 U.S.C. 5705 Records (Medical quality assurance (QA) materials). Medical QA materials, such as monitoring and evaluation reviews and focused reviews, are confidential and privileged and may not be placed in an Evidence File (see 38 U.S.C. 5705(a), 38 CFR 17.501, VHA Directive 1100.18, par. 13b(5), and App. B, par. 2b(4)). If a document has been identified as QA material, consult the facility's QA plan to confirm. If a document that does not qualify as medical QA material is erroneously designated as a 5705 document and included in an Evidence File, the error needs to be corrected by redacting the statement identifying the record as medical QA material.
- c. Title 38 U.S.C. 7332 Records and Similar Documents (that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, Human Immunodeficiency Virus (HIV), or sickle cell anemia). Records that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, HIV, or sickle cell anemia may not be included in an Evidence File (see 38 U.S.C. 7332(a); 42 U.S.C. 290dd-2(a); 38 CFR 1.461). Such materials appear necessary to report (i.e., the file would lack sufficient evidence without such documents), the information must be made anonymous by redacting individual identifiers. To assist the reviewer where more than one patient is involved, individual identifiers may be replaced anonymous patient identifiers, such as Patient W (see App. B, par. 2b(1)).
- d. Employee Drug Testing or Drug and Alcohol Abuse Records. Records that contain the results of an employee's drug test or employee records maintained in connection with drug and alcohol abuse prevention, treatment, and rehabilitation programs and services may not be included in an Evidence File. (With respect to treatment and rehabilitation of Federal employees, see 5 U.S.C. 7361(b), and 7362(b)). If such materials appear necessary to report (i.e., the file would lack sufficient evidence without such documents), the information must be made anonymous by redacting individual identifiers. *NOTE: If it is not possible to both remove this information and redact individual identifiers* (e.g., the positive drug test results of a professional being reported for theft of narcotic medication), contact the VHA Privacy Officer, for guidance.

#### **APPENDIX C**

#### INSTRUCTIONS FOR PRIVACY OFFICERS ON REPORTING FILE REVIEW

#### 1. BACKGROUND

- a. To ensure that its health care professionals meet generally accepted professional standards for patient care, the Department of Veterans Affairs (VA) notifies State Licensing Boards (SLB), charged with licensing health care professionals, when a professional's behavior or clinical practice so substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients (see Veterans Health Administration (VHA) Directive 1100.18, pars. 1-5).
- b. A facility reports a professional to the appropriate SLBs by submitting portions of the Reporting File. The Reporting file consists of the Evidence File (which contains documentation supporting the charges of substandard care), Notice of Intent to Report, and the Response and Rebuttal Resolution Memorandum. The Reporting file is reviewed by a Privacy Officer to ensure that the file is appropriately redacted prior to release. Records that may appear in an Evidence File include: patient health records, including prescription and administration records; documents of administrative investigative boards (AIB); police reports; signed statements and reports of contact from the professional, staff, or patients; facility policies and procedures that identify the standards or requirements breached; and relevant health information specific to the licensed health care professional (see App. B, subpar. 1d).

#### 2. DISCLOSURE AUTHORITY

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorizes VHA to disclose such materials when conducting its health care operations. however; the Privacy Act only permits VHA to release to an SLB, the Reporting File concerning a health care professional pursuant to the professional's prior written consent, a court order or a qualifying request from the SLB (see Title 5 United States Code (U.S.C.) § 552a(b)(7) – the Privacy Act)). The routine use in the "Health Care Provider Credentialing and Privileging Records – VA" system of records (77VA10A4 regarding disclosures to SLBs does not provide authority for the disclosure of the Reporting File. Under the routine use, VA may alert an SLB of incidents suggesting substandard care, without naming the licensed health care professional, and indicate that the Evidence File may be provided pursuant to a qualifying law enforcement request. The release of any more information, including the Evidence File, must be authorized by either a written consent of the professional, court order or a law enforcement request that qualifies under 5 U.S.C. § 552a(b)(7) of the Privacy Act. **NOTE:** For a sample letter that meets the requirements for a proper law enforcement request, see Appendix I.

#### 3. CATEGORIES OF RECORDS AND INFORMATION

a. Individual Identifiers. Information that identifies individual patients, including names, addresses, and social security numbers, and any information that makes the information linkable to an individual must be redacted from all documents. Names of

VA employees may generally remain in the Evidence File but should be redacted when not pertinent. All personal information regarding employees, such as, home addresses, telephone numbers, Social Security Numbers and other personal information must be redacted. To assist the reviewer where more than one patient is involved, individual identifiers may be replaced anonymous identifiers, such as Patient W (see Appendix. B, Paragraph. 2.b.(1).

- b. Title 38 U.S.C. § 5705(a) Records (Medical quality assurance (QA) materials). Medical quality assurance (QA) materials, such as monitoring and evaluation reviews and focused reviews, are confidential and privileged and may not be placed in an Evidence File (see 38 U.S.C. § 5705(a), 38 CFR § 17.501, Paragraph. 13b(5) of this directive, and Appendix B, subparagraph. 3.b.(4)). If a document has been identified as quality assurance material, consult the VA medical facility's Director of quality assurance to confirm. If a document is erroneously designated as a 5705 document and included in an Evidence File, the error needs to be corrected by redacting the statement identifying the record as medical quality assurance material.
- c. Title 38 U.S.C. § 7332 Records and Similar Documents (that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, Human Immunodeficiency Virus (HIV), or sickle cell anemia). Information protected by 38 U.S.C. § 7332 may not be released to the SLB and must be redacted prior to inclusion in the evidence file.
- d. Employee Drugs Testing or Drug and Alcohol Abuse Records. Records that contain the results of an employee's drug test or employee records maintained in connection with drug and alcohol abuse prevention, treatment, and rehabilitation programs and services may not be included in an Evidence File. (see 5 U.S.C. §§ 7361 (b), and 7362 (b)). If such materials appear necessary to report (i.e., the file would lack sufficient evidence without such documents), the information must be made anonymous by redacting individual identifiers. *NOTE:* If it pertains to the subject of the investigation and the identity would therefore be inferred, redacted documents cannot be provided and the information must be withheld in full. (e.g., the positive drug test results of a professional being reported for theft of narcotic medication). Miscellaneous. For details on reviewing the Evidence File, see Appendix B. (check reference if changed). For further guidance, contact the VHA Privacy Officer.

#### APPENDIX D

# SAMPLE NOTICE OF INTENT TO REPORT LICENSED HEALTH CARE PROFESSIONAL

(Certified Mail, Return Receipt Requested)	
(Date)	
Dear:	

It is the policy of the Department of Veterans Affairs (VA) to report to State Licensing Boards (SLB) licensed health care professionals whose clinical practice has significantly failed to meet generally accepted standards of clinical practice so as to raise reasonable concern for the safety of patients. Our legal authority to make these reports is Title 38 United States Code, Sections §§ 501, 7401-7405, 7311; 38 C.F.R. 47.2, and their VA implementing policy, VHA Directive 1100.18, Reporting and Responding to State Licensing Boards, dated January 28, 2021.

Based upon the f	following charges	, we are conside	ering whether,	under these	criteria,
you should be rep	ported to the SLE	<ol><li>Our records ir</li></ol>	ndicate		

**NOTE:** Repeat verbatim the Index of Charges, except for Tab references--do not include patient names.

### (SAMPLE INDEX OF CHARGES)

- a. On December 13, 2016, you treated patient W2345 and wrote that the patient has "unsteady gait and slow speech." On December 14 and 15, 1997, you diagnosed the patient as having a sinus headache. Later, the patient was diagnosed as having a brain tumor. Your misdiagnosis resulted in the patient not receiving proper treatment for several days and constitutes treatment and diagnostic error.
- b. Between approximately July 24 and September 23, 1997, you engaged in a sexual relationship with patient A2598, a member of your therapy group. Your conduct blurred the distinctions between the professional staff and patients and resulted in a relapse of the patient. Your conduct constitutes patient abuse.
- c. On May 25, 1997, you prescribed ampicillin to patient E3456 even though her medical records stated that she was allergic to penicillin. The drug caused the patient to have an adverse reaction which resulted in the hospitalization of the patient. Your actions constitute treatment error.
- d. On August 19, 1997, you went on leave for 2 weeks without transferring care of your patients. This lack of continuity of care resulted in an emergency situation involving patient S4956. His deteriorating condition was unattended for several hours while the nursing staff located a physician who was available and willing to intervene. This constituted patient abandonment. On November 24, 1997, the Sure-Med cabinet recorded that between 0200 and 0600, you withdrew four 2mg tubex of Ativan, one each for patients B40963, G9547, Q4747, and M3419. The medical records for all four

# VHA DIRECITVE 1100.18 APPENDIX D

patients show that each patient received only 1 mg. While you state that you wasted the unused 4 mg, the required procedures for documenting and witnessing controlled substances as contained in Medical Center Policy Document 123-ABC were not observed. This failure to properly account for controlled substances constitutes medication documentation error.

If you have information that you believe should be considered regarding whether VA should report you concerning these matters, please submit such information to the above address within 7-business days from the date of receipt of this letter, to the attention of (insert name), who may be contacted at (000) 123-4567.

Providing information in response to this letter is voluntary. If you do not provide information, a decision concerning whether to report you to the SLB will be made based on available information. Any information you provide will be maintained in VA system of record 77VA10A4, which may be available to the SLB, similar licensing bodies, or to other types of law enforcement authorities under the Privacy Act routine use authority.

(Signature)

VA medical facility Director

#### SAMPLE REBUTTAL RESOLUTION MEMORANDUM

(From a Service Chief or Chief of Staff to an Organizational Head such as a

VA Medical Center Director)

From: Service Chief for Ambulatory Care

Thru: Chief of Staff

To: Director

Subj: Rebuttal Resolution Regarding Proposed Reporting to State Licensing Boards

(SLB) of Jane Doe, R.N.

- 1. By letter of November 10, 20xx, Ms. Doe was notified of our intent to report her to the appropriate State Licensing Boards (SLB) for five concerns which we believe meet the standard for reporting. By letter of December 14, 20xx, Ms. Doe replied to the Intent to Report letter and by letter of January 2, 20xx, an additional reply was received from her attorney. After consideration of that correspondence, I recommend that charge four be dropped as explained below and the other charges be reported as proposed. The adoption of this recommendation resolves all the contested and disputed issues raised in Ms. Doe's response to the Notice of Intent to Report letter.
- 2. Neither Ms. Doe nor her attorney challenged or rebutted the first three charges regarding multiple medication documentation and administration errors, and there is substantial evidence to support those charges. However, both Ms. Doe and her attorney challenge charges four and five regarding diversion of narcotics for personal use and patient mental abuse.
- 3. Ms. Doe denies the fourth charge alleging diversion of narcotics for personal use. The allegation is supported by the five documents under Charge Four: (1) the Sure-Med report that recorded Ms. Doe as the individual removing four Percocet pills on September 9 for patient W9754; (2) the patient's statement that the pills he received did not lessen his pain and those pills did not appear to him to be the usual ones he received; (3) Ms. Doe's documentation in his records that she gave him two pills each at 0100 and 0500; (4) the statement from Dr. Jones that patient W9754 was alert and able to record events accurately; and (5) the September 9 Report of Contact from James Brown that stated that he saw four pills (type unknown) on the night stand of patient W9754 when he first reported for duty at 0730, but the pills were not there after the shift change at 0800. She contends that she gave the medicine as charted, that the pills looked different because they came from a new supplier, and that the medicine observed may have been her own personal medicine that she took before leaving duty. The five documents relied upon do not present any reliable evidence of diversion of the four Percocet pills for personal use. Additionally, while I was able to confirm that we had a new supplier of Percocet pills that looked different, I was unable to confirm if the

new pills were in use on the day in question. Under these circumstances, I do not believe that the charge of diversion for personal use can be sustained and that is the reason for the recommendation that this charge be dropped from any reporting and that all references to the charge be delete from any reports to be made to the SLB.

- 4. The fifth charge was that Ms. Doe mentally abused patient \$3456 by her improper contact and conduct with him when she was a nurse on the psychiatric ward from May through August, 19xx. In her reply, Ms. Doe admits to improper contact and conduct with patient S3456 by her letters, telephone calls, and poems to him, but denies that her conduct constituted "patient mental abuse" as alleged in the Notice of Intent to Report letter. I do not find any merit in the distinctions made by her and her attorney. I believe that there is substantial evidence to report the patient abuse as alleged. Under Charge Five in the Evidence File is an August 15, 199x, letter of proposed removal that contains the same allegations that are in our Letter of Intent to Report. In her August 29, 199x, reply to her proposed removal, Ms. Doe admitted that she sent patient S3456 letters and poems that had romantic overtones and were suggestive of a personal relationship. However, she maintains that her letters and telephone calls were in response to his letters and calls to her. Her reply letter contained her apology for causing him "marital difficulty" and having his therapy team changed. Ms. Doe's admissions must be considered in the context that, during the time of the letters and telephone calls, patient S3456 had just been discharged from three months as an inpatient on the psychiatric ward and had just completed his first month as an outpatient in twice weekly therapy. Ms. Doe abused her professional relationship with patient S3456 and created harm in his personal life based upon the dependent relationship between therapist and patient. and Ms. Doe's knowledge that her telephone calls to patient S3456 at home caused his wife to complain to the Psychiatric Service Chief, which resulted in his reassignment to a new therapy team. Based on these facts, the characterization of Ms. Doe's interactions with patient S3456 as constituting mental patient abuse is reasonable, is supported by substantial evidence, and should not be changed because of Ms. Doe's rebuttal.
- 5. In reaching resolution of the issues raised by the response letter, I have consulted with the supervisory officials who were involved in the initiation of the charges in the Notice of Intent to Report and they are in agreement with my recommendations.

## **APPENDIX F**

# SAMPLE DECISION MEMORANDUM FROM VA MEDICAL FACILITY DIRECTOR (00)

(Date)
From: Director
To: For the Record
Subj: Disclosure to SLB
Name: John Doe, M.D.
Date of Birth: 10/4/36
Occupation: Physician
Last 4 of SSN: XXX-XX-0000
Last Known Address:
Licensure: New York #00000
Maine #0000
n accordance with the authority contained in Title 38 United States Code, §§ 501, 7401-7405; 7311, 38 C.F.R. 47.2, and the implementing policy, VHA Directive 1100.18, have decided, based upon a careful review of the attached State Licensing Board (SLB) Reporting File, that:
There is substantial evidence to make a report to the and SLB regarding John Doe, M.D. for the following:
John Doe, M.D., so substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients, when during his clinical performance as a general staff surgeon, he made multiple diagnostic and treatment errors.
There is NOT substantial evidence to make a report to the SLB regarding John Doe, M.D.
(Signature) VA medical facility Director

### APPENDIX G

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SA	MPLE REPORTING FILE REVIEW MEMORANDUM FROM PRIVACY OFFICER
VI	SN NumberPrivacy Officer]
Dis	closure to State Licensing Board [NAME OF PROFESSIONAL]
Dire	ector, [VA MEDICAL CENTER]
Dat	te:
	The Evidence File associated with the proposal to report [NAME] to the appropriate State Licensing Board (SLB) has been reviewed for compliance with Title 38 U.S.C. Statutes, the Privacy Act 5 U.S.C. 552a and the HIPAA Privacy Rule 45 CFR Parts 160 and 164, for submission to the SLB(s):
	A. I have concluded that the following checked information is not included in the file:
	<ul> <li>a. Patient identifiers (e.g., names, social security numbers, home addresses and any information that makes the file linkable to an individual patient.)</li> <li>b. Records not authorized for release (e.g., medical quality assurance materials confidential and privileged under Title 38 United States Code (U.S.C.) § 5705)</li> <li>c. Employee health records related to drug test results or education, training, treatment, rehabilitation, or research for drug or alcohol abuse</li> <li>d. Personal Information that pertains to any employee that is not relevant and material to the proposed reporting</li> </ul>
	B. VISN PO Recommendation:
	I have reviewed the file and validated that the file is appropriate for submission to the SLB (Only choose if all of the above items are checked) VISN Privacy Officer Signature for recommendation to submit:
	I have reviewed the file and have determined that the file is not appropriate for submission due to inclusion of the following information:

C. The Reporting File may be released to an SLB pursuant to either:

VISN Privacy Officer Signature for recommendation against submission:

[NAME]'s prior

Written consent, court order or a qualifying law enforcement request from the SLB(s) that meets the requirements described in Appendices J and K (Check References if changed) of VHA Handbook 1100.18.

#### **APPENDIX H**

#### SAMPLE REPORTING LETTER TO STATE LICENSING BOARD

Copy of letter to be uploaded into the SLB Reporting SharePoint Site on the VHA Medical Staff Affairs Intranet page.

(Date)		
(Address of SLB)		
Dear	j	

In compliance with applicable authority be advised that there is substantial evidence that Jane Doe, R.N., so significantly failed to meet generally accepted standards of clinical practice to raise reasonable concern for the safety of patients by (Insert summary statement here).

#### SOME EXAMPLES OF SUMMARY STATEMENTS ARE:

- 1. Making repeated and significant medication errors in (transcription) (administration) (documentation);
- 2. Making repeated and significant treatment and diagnostic errors;
- 3. Being unable to meet the health standards for her position;
- 4. Having an intimate personal relationship with a patient;
- 5. Abusing her position by engaging in a (business) (financial) (sexual) relationship with a patient;
- 6. (Verbally) (physically) (emotionally) abusing patients;
- Making repeated (transcription) (administration) (documentation) errors with controlled medications:
- 8. Engaging in\_\_\_\_\_

The following identifying data are submitted:

Date of Birth: March 20, 19xx Social Security Number: 000-00-0000

Last Known Address: 5555 Twin Valley Road

Massachusetts License Number: 000000, Expires 3-20-2002 New York License Number: 09394578599, Expires 3-38-2003

Questions in this regard may be referred to (insert name and title), at (telephone number. If you wish to obtain the relevant information contained in the State Licensing Board Reporting File in this case, please submit a letter to the undersigned, which meets the requirements of 5 U.S.C. § 552a(b)(7) of the Privacy Act, to INSERT VA

# VHA DIRECTIVE 1100.18 APPENDIX H

MEDICAL FACILTIY PRIVACY OFFICER INFORMATION. Such a letter must be on your letterhead stationery; cite the State law giving you authority to take action against professionals who hold a license, certification, or registration; identify the professional about whom information is sought, the records desired, and the law enforcement activity for which the information is sought; and be signed by the head of your SLB or a person who has been designated to act for the head of your SLB. A sample letter and instructions that will permit proper disclosure are enclosed. A Freedom of Information Act (FOIA) request is not sufficient to permit the disclosure of this information by VA.

(Signature)

VA medical facility Director

Enclosure (The enclosure is Appendix I).

# SAMPLE PRIVACY ACT SUBSECTION (b)(7) LAW ENFORCEMENT LETTER FROM STATE LICENSING BOARD (SLB) REQUESTING VA's SLB REPORTING FILE

(Official Letterhead Stationery)

(Date)

Director

**VA Medical Center** 

1234 Veterans Boulevard

Patriotic, USA 55555

RE: John Doe, M.D.

Dear Madame:

Thank you for your recent correspondence of December 1, 200x, regarding John Doe, M.D. A review of our records reflects that Dr. Doe holds an active unrestricted license in this jurisdiction. The Board requests that you submit the relevant portions of the SLB Reporting File to support your conclusion that Dr. Doe failed to conform to generally accepted standards of clinical practice so as to raise reasonable concern for the safety of patients.

As you may know, whenever issues of a professional's competence or harm to patients is raised, the Board has law enforcement authority to review the concerns and take action as may be appropriate to protect the public's health. I understand that the requested information is contained in a system of records and its disclosure is governed by the Title 5 United States Code § 552a(b)(7) of the Privacy Act, which permits the disclosure of the requested information to a governmental agency for a law enforcement activity. This Board is authorized by the (INSERT APPLICABLE AUTHORITY, SUCH AS: Physicians and Nurses Practice Act, found at Section 23.345 of the State Code) to investigate Physicians, Dentists, and Nurses licensed by this State when information is received that substandard care may be occurring and for other purposes set forth in the cited Statute.

(The paragraph in brackets is to be used only when the letter is signed by a designee and not the Board head – See following note.) [The Board's head has delegated to me the power to request records covered by the Privacy Act, and a copy of that delegation is also enclosed.]

Should you have any questions or concerns, please contact me at (123) 345-6789. Thank you for your cooperation.

Sincerely,

VHA DIRECTIVE 1100.18 APPENDIX I

(Signature)
Board head or designee, as appropriate
Enclosures
<b>NOTE:</b> For VA to have Privacy Act disclosure authority, the letter must be signed by the head of the SLB or a person who has been designated to act for the head of the Board. A designee must be an official of sufficient rank to ensure that the request for records has been the subject of high level evaluation of the need for the information. If the request is signed by a designee, a copy of the designation of authority, specifically citing section 552a(b)(7) of the Privacy Act, must be enclosed. The text portion of a sample section 552a(b)(7) Privacy Act delegation from a SLB acceptable to VA follows:
I am the Executive Director and head of the State Board of Nursing. The State Board of Nursing has authority under State Statute Section xx 1234 to investigate and monitor concerns about substandard health care practices. I understand that disclosure of information contained in a system of records is governed by the Privacy Act, 5 U.S.C. § 552a. Section 552a(b)(7) of the Privacy Act permits the disclosure of the requested information to a governmental agency for a law enforcement activity as set forth in State Statute ABC found at Section XX of the State Code.
To assist me in carrying out my duties under the Statute, I am delegating to the persons listed below my authority to request such information on behalf of the Board:
Deputy Executive Director Associate Executive Director for Investigations Associate Executive Director for Prosecution
This delegation is effective on, 20xx. The current status of any person using the above titles may be verified by calling the Board's office at (123) 456-7898.
Sincerely yours,
Mary Jones Smith, RN, MS, Ds N. Executive Director

#### PROVIDER EXIT REVIEW

This document is to be used by the first- or second-line supervisor at the time a licensed provider departs facility. This will serve as documentation of the initial review in accordance with this directive, Reporting to State Licensing Boards. This is to be completed for any licensed provider who has been credentialed and appointed including but not limited to full-time, part-time intermittent, volunteer, and contract staff. This requirement applies to ALL licensed providers, e.g., physicians, registered nurses, social workers, psychologists, dentists, etc. \_\_\_\_\_ within 7-business davs Complete and return this form to of provider leaving this facility. A copy is to be maintained at the facility and a copy scanned into the provider's electronic credentialing file on the Personal Profile screen before inactivating the file. Provider's Name: \_\_\_\_\_\_Service: \_\_\_\_\_ Date of Clearance from Facility: Resigned/ Retired \_\_\_\_\_ Reason: Transferred to another VA: Facility: Resigned while under Investigation Terminated/ Removed for Clinical Care Concerns \_\_\_\_\_\_ Terminated for Conduct/ Administrative/ Professionalism Issues Contract Ended \_\_\_\_\_ Other \_\_\_\_ -Care provided by this licensed health care professional: (CHECK ONE ITEM BELOW) Met generally accepted standards of clinical practice, and there was no concern for the safety of patients. (The level of ability and practice expected of competent professional, as well as the moral and ethical behavior necessary to carry out those responsibilities.) SLB reporting is not indicated. Met generally accepted standards of clinical practice, however, if asked for recommendation, I would recommend proctoring related to . SLB reporting is not indicated. Met generally accepted standard of clinical practice, however, there is documented record and evidence of personnel actions taken due to: \_\_\_\_Conduct Issues

Professionalism Issues	
Administrative Issues	
Other:	

\_\_\_\_\_Failed to meet generally accepted standards of practice as to raise reasonable concern for the safety of patients. (When, given all the circumstances, a reasonable person would be concerned for the safety of patients treated by the licensed health care professional.) SLB reporting IS indicated and is to be immediately initiated/ has been initiated. If this is selected, there must be documented, substantial evidence of provider failing to meet standard of care.

**NOTE:** If selected, this form must be signed by service chief, respective "quad member" and Director.

The following are examples of substandard actions that could provide a basis for reasonable concern for the safety of patients, and thus would warrant a **COMPREHENSIVE REVIEW** for the potential reporting in accordance with this directive, Reporting State Licensing Board):

- 1. Significant deficiencies in clinical practice, for example, lack of diagnostic or treatment capability; multiple errors in transcribing, administering or documenting medications; inability to perform clinical procedures considered basic to the performance of one's occupation; or performing procedures not included in one's clinical privileges in other than emergency situations;
  - 2. Patient neglect or abandonment;
- 3. Mental health impairment sufficient to cause the individual to make judgment errors affecting patient safety, to behave inappropriately in the patient care environment, or to provide unsafe patient care;
- 4. Physical health impairment sufficient to cause the individual to provide unsafe patient care;
- 5. Substance abuse when it affects the individual's ability to perform appropriately as a health care provider in the patient care environment.
  - 6. Falsification of credentials;
  - 7. Falsification of medical records or prescriptions;
  - 8. Theft of drugs;
  - 9. Inappropriate dispending of drugs;
- 10. Unethical behavior or moral turpitude (such as sexual misconduct toward any patient involved in VA health care;
- 11. Patient abuse, including mental, physical, sexual, and verbal abuse, and including any action or behavior that conflicts with a patient's rights identified in the Title 38, Code of Federal Regulations (CFR); intentional omission of care; willful violations of

### VHA DIRECITVE 1100.18 APPENDIX J

a patient's privacy; willful physical injury or intimidation, harassment or ridicule of a patient; or

12. Falsification of research findings, regardless of where the research was carried out or the funding source as long as involved in some aspect of operations of the VA.

FIRST- OR SECOND-LINE SUPERVISOR SIGNATURE	DATE
<del>-</del>	
ROUTING AND SIGNATURES IF "FAILED TO MEET" Is Selected:	
The following signatures are only required if "failed to meet" was form must also be signed by the service chief, respective "quad Director	
Service Chief:	
COS/ AD/ ADPCS:	
Director:	-
COMMENTS:	